

REMARKS

Reconsideration of the application is respectfully requested.

1) The Office Action imposes a restriction requirement apparently between claims 34-45 drawn to a dual-purpose wound dressing and claims 50-54 drawn to a method of using a dual-purpose wound dressing. Applicant respectfully traverses the restriction requirement.

The Office Action states that restriction is required contending that the product (the dual-purpose wound dressing) as claimed can be used in a materially different process of using that product, stating specifically that: "In the instant case, the product can be used as a transdermal product to deliver drugs." However, in order for the claimed product to be used as a transdermal product to deliver drugs, the method of use as claimed by the Applicant would be used. Specifically, in using the claimed product as a transdermal product to deliver drugs, the method would include providing the claimed multilayered composite structure as set out in Applicant's claim 50, choosing the outer wound contacting surface desired to be applied to the wound (in the Examiner's example a person's skin which would comprise the equivalent of a wound site in the Examiner's example), applying the dressing to the wound (the skin in the Examiner's example) with the chosen outer wound contacting surface contacting the wound (e.g., skin) to provide the wound healing characteristics of the chosen outer wound contacting surface (the drug side of the dressing) to the wound (e.g. the skin).

In each case the dual-purpose wound dressing would be applied, the specific outer surface would be chosen that was capable of providing the desired characteristics (in the Examiner's example, the side capable of delivering the drug transdermally) to the person to which the dressing is to be applied, and the dressing would be applied with the chosen outer

surface being placed in contact with the person to which the dressing is being applied.

Accordingly, it would appear that in order to practice the Examiner's proposed process, Applicant's process would be used. Accordingly, withdrawal of the restriction requirement is respectfully solicited.

- 2) Applicant appreciates the indication by the Examiner that the rejection of claim 41 under 35 U.S.C. Section 112, 2nd paragraph, has been withdrawn.
- 3) Claims 34 – 36 and 45 are rejected under 35 U.S.C. §102(e) as being anticipated by Lindqvist et al. (6,051,747). Applicant respectfully traverses this rejection.

The Examiner states in the Office Action that Lindqvist et al. disclose a wound dressing comprising three layers, a first gel layer 3, a second polyurethane foam layer 2, and a third liquid-impervious layer 5 on a side of the dressing opposite the side of the dressing having the gel layer 3, and that "The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby." Further, the Examiner states that "...the foam layer is not sandwiched as argued by applicant since Lindqvist's clearly discloses that the 'gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound'" and "Thus, the foam does have a wound-contacting surface since the gel layer or adhesive layer does not cover the entire surface of the foam layer."

However, contrary to the Examiner's interpretation of Lindqvist et al., Lindqvist et al. specifically state the following:

The gel layer also forms a spacing layer which prevents the foam material from coming into direct contact with the wound or skin of the wearer.

(See Lindqvist et al. at Column 2, lines 54-56.)

Further, Lindqvist et al. at Column 1, lines 41-43, state:

Even a thin gel layer will function as a spacer layer, because it covers the end part of the hole walls and therewith prevents contact between foam material and skin,...

Clearly, contrary to the Examiner's contention, the foam layer 2 of Lindqvist et al. does not have a wound contacting surface. While Lindqvist et al. have an absorbent foam layer 2, Lindqvist et al.'s foam layer 2 does not come into direct contact with a patient's wound since it is sandwiched between two other layers (the gel layer 3 and the liquid-impervious layer 5) in the Lindqvist et al. wound dressing. Accordingly, Lindqvist et al.'s dressing is structurally distinguishable from Applicant's claimed invention defined in Applicant's claim 34.

Applicant's claim 35, 36, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

4) Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Hofeditz (4,552,138). Applicant respectfully traverses this rejection.

Unlike Applicant's invention recited in Applicant's claim 34, Hofeditz does not disclose a dual-purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side.

While Hofeditz has a gel layer having an outer wound contacting surface, Hofeditz, in contrast to Applicant's invention, has a foam layer as an intermediate or cover layer. Hofeditz does not disclose a foam layer having an outer wound contacting surface having wound healing characteristics, as called for by Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully requested.

Applicant's claims 36, 40, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

5) Claims 34 – 36, 38, 42 – 43, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (5,681,579). Applicant respectfully traverses this rejection.

In contrast to Applicant's invention recited in Applicant's claim 34, Freeman, does not disclose a dual-purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side. Freeman discloses a various wound dressings comprising a polymeric support layer and an occlusive backing layer overlaying the support layer. Typically, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient. Freeman's occlusive backing layer does not have an outer wound contacting surface having wound healing characteristics, as called for in Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully solicited.

Applicant's claims 35, 36, 38, 42-43, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

6) Claims 37 and 39 – 42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindqvist et al. (6,015,747) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent 4,832,009. Applicant respectfully traverses this rejection.

None of the cited references teaches or suggests, either alone or in combination, Applicant's dual-purpose wound dressing having a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure.

Neither Lindqvist nor Lorenz nor US Patent No. 4,832,009 discloses a wound dressing having both a first wound contacting side having an outer wound contacting surface having wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side. There is no suggestion to be gleaned from either reference to produce a wound dressing that has **both** a first wound contacting side having an outer wound contacting surface that has wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from a wound healing characteristics of the outer surface of the first side. Lindqvist, Lorenz, and US Patent No. 4,832,009 show dressings having only one outer wound contacting

surface for contacting a wound, and there is no suggestion in these references to use the dressings of the references as intended and also in an "up-side down" orientation, if desired, so as to provide a choice of wound healing characteristics from one dressing to a wound.

As pointed out above, Lindqvist discloses a dressing that has only one outer wound contacting surface. Lorenz also has only one outer wound contacting surface, with only the gel layer of the dressing being applied to the patient's wound. In Lorenz, the substrate layer merely provides reinforcement, a gas and liquid barrier, a support with gas and liquid permeability, and/or protection for the gel and the area of treatment, etc. In Lorenz, if the tacky gel layer is not applied to the entire substrate layer, the non-gel coated inner surface of the substrate layer may be provided with an additional adhesive which contacts the intact skin while the absorbent adhesive gel layer contacts the wound. Similarly, US Patent No. 4,832,009 has only one wound contacting surface. Accordingly, there is nothing in the references, either taken alone or in combination, that suggests a wound dressing having two different outer wound contacting surfaces having two different wound healing characteristics.

Moreover, as explained above, Lindqvist has its foam layer sandwiched between the two outer layers of the Linqvist dressing, and neither Lorenz nor US Patent No. 4,832,009 remedy the claim element deficiency of Lindqvist.

Regarding the Examiner's statement that ". . . the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions" with regard to claim 41, Applicant notes that claim 41 does not merely recite an aesthetic design change. Applicant appreciates the Examiner's statement that the addition of pigment is a structural change. The pigmented adhesive layer provides a visual indicator for

differentiating one side of the dressing from the other side of the dressing in the field. Also, none of the references mixes pigment into the adhesive connecting a translucent layer to an opaque layer to distinguish one side of the dressing from the other side of the dressing.

7) Claim 44 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lindqvist et al. (6,015,747) by itself or in view of Freeman (5,681,579). Applicant respectfully traverses this rejection.

As explained above, Lindqvist has its foam layer sandwiched between the two outer layers of the Lindqvist dressing, and Freeman does not remedy the claim element deficiency of Lindqvist.

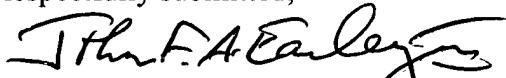
8) Claims 37, and 39-41 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent No. 4,832,009. Applicant respectfully traverses this rejection.

Regarding the combination of Freeman in view of Lorenz, and as evidenced by US Patent No. 4,832,009, the suggestion to be drawn from these references, either taken alone or in combination, is the production of a “single-sided” dressing. These references show an adhesive layer being provided to the dressing so that it may only be used in one orientation, adhesive side down. The combination of the references fails to show any suggestion for producing a “two-sided” dressing since the disclosures of these references only show “single-sided” dressings.

9) If necessary, an appropriate extension of time to respond is respectfully requested.

10) The Commissioner is authorized to charge any additional fees which may be required to Patent Office Deposit Account No. 05-0208.

Respectfully submitted,



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